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| 10/790,576 | 03/01/2004 | William H. Eby | 1421-159 | 9869 |

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JONDLE & ASSOCIATES P.C.
858 HAPPY CANYON ROAD SUITE 230
CASTLE ROCK, CO 80108

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| EXAMINER |
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MCELWAIN, ELIZABETH F

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| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,576

Applicant(s)

EBY, WILLIAM H.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/15/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-29 are pending.

Claims 1, 6, 22, 23 and 28 are objected to for the inclusion of a blank line where the ATCC Accession number should be.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6, 22, 23 and 28, and claims 2-5, 7-21, 24-27 and 29 dependent thereon, are indefinite in the recitation of "seed of soybean line designated 0509243", given that a name does not clearly identify the claimed soybean cultivar and seed, and does not set forth the metes and bounds of the claimed invention. Since the name 0509243 is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no written description of the soybean plant that encompasses all of its traits. Amending the claims to recite the ATCC deposit number would overcome the rejection.

Claim 28 is indefinite in the recitation of "A method of modifying fatty acid metabolism or modified carbohydrate metabolism into soybean", since it is unclear what this means.

Claims 28 and 29 are indefinite and confusing given that the claims state that the resulting plant will comprise "the nucleic acid molecule and has all of the physiological and morphological characteristics of soybean line 0509243 listed in Table 1". However, the

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existence of the introduced nucleic acid molecule suggests that there would be at least one other characteristic or modified characteristic in the resultant plant, which would not be consistent with the wording of the claim.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to hybrid soybean seeds and plants. The claims are drawn to hybrid soybean seeds and plants produced from said, wherein one of the parents is 0509243 and the other parent plant is not specified. The hybrid plants are not defined by genomic structure or by phenotypic characteristics, and it is unclear what characteristics of 0509243 would be present in the claimed hybrid seeds and plants. Due to the segregation and recombination of the parent genomes during meiosis, one cannot predict what traits or combinations of traits will be passed on to any given hybrid seed and plant. In fact, *each* hybrid seed derived from a cross between two genetically distinct parent plants will have unique combinations of characteristics. Therefore, the claimed invention lacks an adequate written description.

See *University of California v. Eli Lilly*, 119 F.3d 1567, 43 USPQ 2d 1405 (Fed. Cir. 1997), where it states: “[a] written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula,

[or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials.”

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claims 1-29 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants intend to deposit seeds for 0509243 at the ATCC, but there is no indication that the seeds have been deposited and there is no indication in the specification as to public availability. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance

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of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer; (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

In addition, with regard to claim 20, the specification does not provide support for transforming the claimed soybean plant with a transgene encoding a stearyl-ACP desaturase, but rather teaches transforming the claimed soybean plant with DNA encoding an antisense sequence of a stearyl-ACP desaturase. Amendment of the claim to reflect what is disclosed in the specification would overcome the rejection.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-29 are rejected on the ground of nonstatutory double patenting over claims 1-18 of U. S. Patent No. 6,777,594 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claimed plants and seeds appear to be the same as those already patented in U. S. Patent No. 6,777,594, given the characteristics set forth in the specification.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-29 are rejected on the ground of nonstatutory double patenting over claims 1-18 of U. S. Patent No. 6,777,594 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the claimed plants and seeds appear to be the same as those already patented in U. S. Patent No. 6,777,594, given the characteristics set forth in the specification.

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Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent 6,235,978.

Applicants have claimed 0509243 soybean and a hybrid plant produced by crossing 0509243 soybean with a different soybean plant. However, it appears that the claimed plants and seeds are the same as the prior art soybean cultivar of U.S. Patent 6,235,978, given that each has the same characteristics, including: Roundup resistance, purple flowers, brown hilum, and tan pod, for example. Alternatively, if the claimed plants and seeds of 0509243 are not identical to

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the soybean of U.S. Patent 6,235,978, then it appears that the soybean of U.S. Patent 6,235,978 only differs from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 0509243. Thus the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by U.S. Patent 6,235,978 soybean.

Claims 1-29 are rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent 6,777,594.

Applicants have claimed 0509243 soybean and a hybrid plant produced by crossing 0509243 soybean with a different soybean plant. However, it appears that the claimed plants and seeds are the same as the prior art soybean cultivar of U.S. Patent 6,777,594, given that each has the same characteristics, including: Roundup resistance, purple flowers, brown hilum, and tan pod, for example. Alternatively, if the claimed plants and seeds of 0509243 are not identical to the soybean of U.S. Patent 6,777,594, then it appears that the soybean of U.S. Patent 6,777,594 only differs from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 0509243. Thus the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by U.S. Patent 6,777,594 soybean.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-09750975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM